Claims 1-6 are therefore presently pending in the case. For the convenience of the Examiner, a clean copy of the pending claims is attached hereto as **Exhibit A**. In compliance with 37 C.F.R. § 1.121(c)(1)(ii), a marked up copy of the original claims is attached hereto as **Exhibit B**.

II. Support for the Amended Claim

Claims 1, 3 and 5 have been amended to further clarify the claim, and to recite that the isolated nucleic acid molecule comprises the respective full length nucleotide sequences. Support for these claims can be found throughout the specification as originally filed, with particular support being found at least in claims 1, 3 and 5 and SEQ ID NOS: 1, 3 and 5, as originally filed and in Section 5.1.

Claims 2, 4 and 6 have been amended to further clarify the claim, and to recite highly stringent conditions. Amendment of Claims 2, 4 and 6 find support throughout the specification as originally filed, with particular support and a definition of highly stringent hybridization being found at page 3, lines 9-15.

As the amendments to Claims 1-6 are fully supported by the specification and claims as originally filed, they do not constitute new matter. Entry therefore is respectfully requested.

It will be understood that no new matter is included within the amended claim.

III. Title Objection

The Examiner objects to title as being allegedly not descriptive. The title has therefore been amended to read "Novel Human Channel Protein and Polynucleotides Encoding the Same".

IV. Rejection of Claims Under 35 U.S.C. § 101

The Action first rejects claims 1-6 under 35 U.S.C. § 101, as allegedly lacking a patentable utility. Applicants respectfully traverse.

The Action gives a number of reasons for the alleged lack of utility. The Action states that the specification does not set forth a specific level of sequence identity shared over the complete sequence. Applicant submits that this would be an academic exercise as such identity would only evidence that the molecule of the present invention is indeed novel.

The Action also states that "no information is provided regarding the conservation of any particular domains which are required for transporter function or which are characteristic of specific

types of transporter proteins." (Action at page 3). This is misplaced, as it is well established that "an inventor is not required to understand the theory of how his invention works". *Micro Motion, Inc. v. Exac Corp.*, 16 USPQ2d 1001, 1013 (Cal. 1990).

The question of utility is a straightforward one. As set forth by the Federal Circuit, "(t)he threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip Inc. v. Orange Bang Inc.*, 51 USPQ2d 1700 (Fed. Cir. 1999) (citing *Brenner v. Manson*, 383 U.S. 519, 534 (1966)). Additionally, the Federal Circuit has stated that "(t)o violate § 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992), emphasis added. *Cross v. Iizuka* (224 USPQ 739 (Fed. Cir. 1985); "*Cross*") states "any utility of the claimed compounds is sufficient to satisfy 35 U.S.C. § 101". *Cross* at 748, emphasis added. Indeed, the Federal Circuit recently emphatically confirmed that "anything under the sun that is made by man" is patentable *(State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 47 USPQ2d 1596, 1600 (Fed. Cir. 1998), citing the U.S. Supreme Court's decision in *Diamond vs. Chakrabarty*, 206 USPQ 193 (S.Ct. 1980)).

The legal test for utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be credible or believable. According to the Examination Guidelines for the Utility Requirement, if the applicant has asserted that the claimed invention is useful for any particular purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, the Examiner should not impose a rejection based on lack of utility (66 Federal Register 1098, January 5, 2001).

In *In re Brana*, (34 USPQ2d 1436 (Fed. Cir. 1995), "*Brana*"), the Federal Circuit admonished the P.T.O. for confusing "the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption". *Brana* at 1442. The Federal Circuit went on to state:

> At issue in this case is an important question of the legal constraints on patent office examination practice and policy. The question is, with regard to pharmaceutical inventions, what must the applicant provide regarding the practical utility or usefulness of the invention for which patent protection is sought. This is not a new issue; it is one which we would have thought had been settled by case law years ago.

Brana at 1439, emphasis added. The choice of the phrase "utility or usefulness" in the foregoing quotation is highly pertinent. The Federal Circuit is evidently using "utility" to refer to rejections under 35 U.S.C. § 101, and is using "usefulness" to refer to rejections under 35 U.S.C. § 112, first paragraph. This is made evident in the continuing text in *Brana*, which explains the correlation between 35 U.S.C. §§ 101 and 112, first paragraph. The Federal Circuit concluded:

> FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

Brana at 1442-1443, citations omitted. In assessing the question of whether undue experimentation would be required in order to practice the claimed invention, the key term is "undue", not "experimentation". *In re Angstadt and Griffin*, 190 USPQ 214 (C.C.P.A. 1976). The need for some experimentation does not render the claimed invention unpatentable. Indeed, a considerable amount of experimentation may be permissible if such experimentation is routinely practiced in the art. *In re Angstadt and Griffin, supra*; *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). As a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988).

While such information is clearly not a prerequisite to patentability, it can be disclosed that the novel protein of the present invention contains an amino-terminus PDZ actin binding domain as is found in, for example, APXL and shroom related proteins (Accession Nos: Q13796, BAB84689 and NP065910). The carboxy terminus of the protein has ATP binding and ATPase (V type) motif domains. The novel protein of the present invention is a part of a macromolecular complex of proteins forming a channel complex, its role is most likely to anchor the complex to the membrane. This type of activity has also been described for APX (Zuckerman *et al.*, 1999, J.Biol.Chem. *274*: 23286-23285) and it is known to those skilled in the art that most membrane channels are multimeric macromolecular structures that incorporate a number of protein components. Thus the assertions regarding the protein of the present invention are credible.

Given the legal test for utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be credible or believable, this is clear evidence that those skilled in the art would have recognized the function and activity of the protein encoded by the sequences of the present invention, there can, therefore, be no question that Applicants' asserted utility for the described sequences is "credible." As such, the scientific evidence clearly establishes that Applicants have described an invention whose utility is in full compliance with the provisions of 35 U.S.C. § 101, and the Examiner's rejection should be withdrawn.

Although the above discussion is believed to be dispositive of the utility issue, the Applicants would like to further direct the Examiner's attention to the parts of the specification (Sections 5.0 and 5.1) that describe the use of sequences in a gene chip format to provide a high throughput analysis of the relevant cellular "transcriptome".

Evidence of the "real world" substantial utility of the present invention is provided by the fact that there is an entire industry established based on the use of gene sequences or fragments thereof in a gene chip format. Perhaps the most notable gene chip company is Affymetrix. However, there are many companies which have, at one time or another, concentrated on the use of gene sequences or fragments, in gene chip and non-gene chip formats, for example: Agilent Technologies, Gene Logic, ABI-Perkin-Elmer, HySeq and Incyte. In addition, one such company, Rosetta Inpharmatics, was viewed to have such "real world" value that it was acquired by large pharmaceutical company, Merck & Co., for substantial sums of money (net equity value of the transaction was $620 million). The "real world" substantial industrial utility of gene sequences or fragments would, therefore, appear to be widespread and well established. The sequences of the present invention describe a novel gene encoding a transporter and provide a unique identifier of the corresponding gene. Such gene chips clearly have utility, as evidenced by hundreds of issued U.S. Patents, such as U.S. Patent Nos. 5,445,934, 5,556,752, 5,744,305, 5,837,832, 6,156,501 and 6,261,776. The present nucleotide sequences encode a novel human channel protein as detailed throughout the specification. Therefore, as the present sequences are specific markers of the human genome, and such specific markers are targets for the discovery of drugs that are associated with human disease, those of skill in the art would instantly recognize that the present nucleotide sequences would be an ideal, novel candidate for assessing gene expression using such gene chips.

The Examiner is further requested to consider that, given the huge expense of the drug discovery process, even negative information has great "real world" practical utility. Knowing that a given gene is not expressed in medically relevant tissue provides an informative finding of great value to industry by allowing for the more efficient deployment of expensive drug discovery resources. Such practical considerations are equally applicable to the scientific community in general, in the time and resources that are not wasted chasing what are essentially scientific dead-ends (from the perspective of medical relevance). Clearly, compositions that enhance the utility of such gene chips, such as the presently claimed nucleotide sequences, must in themselves be useful. Moreover, the presently described novel transporter provides uniquely specific sequence resources for identifying and quantifying full length transcripts that were encoded by the corresponding human genomic locus. Accordingly, there can be no question that the described sequences provide an exquisitely specific utility for analyzing gene expression.

Yet another example of the utility of the present invention is in expanding the utility of data coming from the human genome project. Persons of skill in the art, as well as thousands of venture capitalists and investors, readily recognize the utility, both scientific and commercial, of genomic data in general, and specifically human genomic data. All current therapeutics directly or indirectly interact with biological sequences encoded by the human genome, and virtually all future human therapeutics shall do likewise. Consequently, billions of dollars have been invested in the human genome project, resulting in useful genomic data (see, *e.g.*, Venter *et al.*, 2001, Science *291*:1304). The results have been a stunning success, as the utility of human genomic data has been widely recognized as a great gift to humanity (see, *e.g.*, Jasny and Kennedy, 2001, Science *291*:1153). Clearly, the usefulness of human genomic data, such as the presently claimed nucleic acid molecules, is substantial and credible (worthy of billions of dollars and the creation of numerous companies focused on such information) and well-established (the utility of human genomic information has been clearly understood for many years).

Although Applicants need only make one credible assertion of utility to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gottlieb*, 140 USPQ 665 (C.C.P.A. 1964); *In re Malachowski*, 189 USPQ 432 (C.C.P.A. 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988)), as a further example of the utility of the presently claimed polynucleotides, the Examiner is respectfully reminded that only

a minor percentage of the genome actually encodes exons that in-turn encode polypeptide sequences. The presently described cDNAs provide biologically validated empirical data (*e.g.*, showing which sequences are transcribed, spliced, and polyadenylated) that *specifically* define that portion of the corresponding genomic locus that actually encodes exon sequence. Equally significant is that the described cDNA sequences define which exons are actually spliced together to produce an active transcript (*i.e.*, such sequences are generally required to conclusively identify functional exon splice-junctions). The Applicants submit that one skilled in the art would have clearly understood that the above *substantial and specific* utilities as inherent features of the presently described sequences.

For the many convincing reasons described above, the present invention clearly has specific, substantial, credible and well established utility. Therefore, Applicants submit that the rejection of claims 1-6 under 35 U.S.C. § 101 has been overcome and the Examiner is respectfully requested to withdraw the pending rejection of claims 1-6 under 35 U.S.C. § 101.

V. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

The Action rejects claims 1-6 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the invention, as the invention allegedly is not supported by a specific, substantial, and credible utility or a well-established utility. Applicants respectfully traverse.

Applicants submit that as claims 1-6 have been shown to have "a specific, substantial, and credible utility", as detailed in section IV above, the present rejection of claims 1-6 under 35 U.S.C. § 112, first paragraph, cannot stand.

Applicants therefore request that the rejection of claims 1-6 under 35 U.S.C. § 112, first paragraph, be withdrawn.

VI. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claims 1-6 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse.

While applicants amendment of claims 1, 3 and 5 to read on full-length molecules essentially obviates this rejection, applicant notes that the written description requirement was met by the application as originally filed. 35 U.S.C. § 112, first paragraph, requires that the specification contain a written description of the invention. The Federal Circuit in *Vas-Cath Inc. v. Mahurkar* (19 USPQ2d 1111 (Fed. Cir. 1991); "*Vas-Cath*") held that an "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*." *Vas-Cath*, at 1117, emphasis in original. However, it is important to note that the above finding uses the terms reasonable clarity to those skilled in the art. Further, the Federal Circuit in *In re Gosteli* (10 USPQ2d 1614 (Fed. Cir. 1989); "*Gosteli*") held:

> Although [the applicant] does not have to describe exactly the subject matter claimed, ... the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.

Gosteli at 1618, emphasis added. Additionally, *Utter v. Hiraga* (6 USPQ2d 1709 (Fed. Cir. 1988); "*Utter*"), held "(a) specification may, within the meaning of 35 U.S.C. § 112 ¶1, contain a written description of a broadly claimed invention without describing all species that claim encompasses" (*Utter*, at 1714). Therefore, all Applicants must do to comply with 35 U.S.C. § 112, first paragraph, is to convey the invention with reasonable clarity to the skilled artisan.

Further, the Federal Circuit has held that an adequate description of a chemical genus "requires a precise definition, such as by structure, formula, chemical name or physical properties" sufficient to distinguish the genus from other materials. *Fiers v. Sugano*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993; "*Fiers*"). *Fiers* goes on to hold that the "application satisfies the written description requirement since it sets forth the ... nucleotide sequence" (*Fiers* at 1607). In other words, provision of a structure and formula - the nucleotide sequence - renders the application in compliance with 35 U.S.C. § 112, first paragraph.

More recently, the standard for complying with the written description requirement in claims involving chemical materials has been explicitly set forth by the Federal Circuit:

> In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. *Univ. of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Thus, a claim describing a genus of nucleic acids by structure, formula, chemical name or physical properties sufficient to allow one of ordinary skill in the art to distinguish the genus from other materials meets the written description requirement of 35 U.S.C. § 112, first paragraph. As further elaborated by the Federal Circuit in *Univ. of California v. Eli Lilly and Co.*:

> In claims to genetic material ... a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA', without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art cannot, as one can do with a fully described genus, visualize or recognize the identity of members of the genus. (Emphasis added)

Thus, as opposed to the situation set forth in *Univ. of California v. Eli Lilly and Co.* and *Fiers*, the nucleic acid sequences of the present invention are not distinguished on the basis of function, or a method of isolation, but in fact are distinguished by structural features - a chemical formula, *i.e.*, the *sequence itself.*

Using the nucleic acid sequences of the present invention (as set forth in the Sequence Listing), the skilled artisan would readily be able to distinguish the claimed nucleic acids from other materials on the basis of the specific structural description provided. Polynucleotides comprising the nucleotide sequence of SEQ ID NOS: 1, 3 and 5, or a nucleotide sequence that encodes SEQ ID NOS: 2, 4 and 6, are within the genus of the instant claims, while those that lack this structural feature lie outside the genus. Claims 1-6 thus meet the written description requirement. If one knows the full-length sequences (which are described in SEQ ID NOS: 1-6 of the Sequence Listing), one also knows a fragment comprising 24 contiguous nucleotides derived from said sequences.

For each of the foregoing reasons, Applicants submit that the rejection of claims 1-6 under 35 U.S.C. § 112, first paragraph, has been overcome, and that amendment of claims 1-6 has rendered this rejection moot. Therefore, Applicants respectfully request that the rejection of claims 1-6 under 35 U.S.C. § 112, first paragraph for failing to meet written description requirements be withdrawn.

The Action next rejects claims 1-6 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the invention.

In the first instance, claims 1-6 are said to be indefinite due to the use of the term "NHP". While Applicant believes that the original claims were definite. Amendment of claims 1-6 has removed the term NHP and this rejection is thus avoided.

In the second instance, claims 1-6 are said to be indefinite due to the use of the phrase "nucleotide sequence first disclosed in the NHP gene" and "nucleotide sequences uniquely disclosed in the NHP gene". Again, while Applicant believes that the original claims were definite, amendment of claims 1-6 has removed these phrases and this rejection is thus avoided. Therefore, Applicants respectfully request that the rejection of claims 1-6 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the invention be withdrawn.

The Action next rejects claims 2, 4 and 6 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the invention. The Action alleges that claims 2, 4 and 6 are indefinite based on the phrase "hybridizes under stringent conditions". Although Applicants believe that this claim as originally filed sufficiently points out and distinctly claims the invention, in order to more rapidly progress the case to allowance, Applicants have amended Claims 2, 4 and 6 to specify "highly" stringent conditions. Highly stringent conditions for full length molecules are defined in the specification on page 3, lines 9-15. Applicants, therefore, respectfully submit that this rejection has been avoided by Applicant's amendment of Claim 2 to specify "highly" stringent conditions. Accordingly, the Examiner is respectfully requested to withdraw the pending rejection of Claims 2, 4 and 6 under 35 U.S.C. § 112, second paragraph.

VII. Rejection of Claims Under 35 U.S.C. § 102

The standard for anticipation under 35 U.S.C. section 102(a) is strict identity. Anticipation under § 102 can only be established by a single prior art reference that teaches each and every element of the claimed invention. *Structural Rubber Products Co. v. Park Rubber Co.* 223 USPQ 1264 (1984).

Claims 1 and 2 stand as rejected under 35 U.S.C. section 102(a) as being allegedly anticipated by Strausberg (Accession number AI300504; reference "BH"). The rejection of Claim 1 has been respectfully avoided by the amendment of Claim 1 to read on the full-length nucleic acid sequence of

SEQ ID NO: 1. The sequence of Strausberg matches only 159 of a total of 573 nucleic acids of SEQ ID NO:1 and that match is in the plus/minus orientation. Thus, the nucleic acid sequence of Strausberg does not encode the same amino acid sequence as, even that small sequence of SEQ ID NO:1 which it contains.

The rejection of Claim 2 as being allegedly anticipated by Strausberg (Accession number AI300504; reference "BH") is in error. The Examiner's rejection of Claim 2 under Strausberg is based solely on the hybridization element of claim and Claim 2 contains 2 limitations. Amended Claim 2 describes an isolated nucleic acid molecule comprising a human nucleotide sequence that:(a) encodes the amino acid sequence shown in SEQ ID NO: 2; and(b) hybridizes under highly stringent conditions to the nucleotide sequence of SEQ ID NO: 1 or the complement thereof. It is doubtful that the sequence of Strausberg would hybridize under stringent conditions to the sequence of SEQ ID NO:1, as it matches only 159 of a total of 573 nucleic acids of SEQ ID NO:1. Additionally, as claim 2 has been amended such that hybridization conditions are now highly stringent, this hybridization becomes even less likely. Even if one were to accept that the Strausberg sequence would hybridize under highly stringent conditions to SEQ ID NO:1, it is clear that Strausberg does not teach or suggest each and every element of amended Claim 2. The examiner does not allege, nor would Strausberg be expected to encode the amino acid sequence disclosed in SEQ ID NO: 2, as the matching sequence is less than a third (159/573) of the full-length sequence described in SEQ ID NO:1 and to make maters worse, the orientation of that match is plus/minus. Lacking such disclosure, it is largely irrelevant whether or not the sequence described by Strausberg *might* hybridize to the SEQ ID NO:1 under stringent or highly stringent condition. Clearly Strausberg has not described or suggested each and every element of amended or original Claim 2 as the nucleic acid sequence of Strausberg cannot encode the amino acid sequence of SEQ ID NO: 2. Applicants, therefore, submit that the rejection of claims 1-2 under 35 U.S.C. § 102(a) under Strausberg has been both avoided and overcome and respectfully request withdrawal of the rejection.

Claim 2 also stands rejected under 35 U.S.C. section 102(a) as being allegedly anticipated by Hair *et al.* (U.S. Patent No. 6,300,127). Amended Claim 2 describes an isolated nucleic acid molecule comprising a human nucleotide sequence that:(a) encodes the amino acid sequence shown in SEQ ID NO: 2; and(b) hybridizes under highly stringent conditions to the nucleotide sequence of

SEQ ID NO: 1 or the complement thereof. The Action states (at page 10, line 5) "Hair *et al.*, discloses a LIM nucleic acid molecule comprising a nucleotide fragment which shares identity with instant SEQ ID NO:1." This fragment does not however encode the amino acid sequence shown in SEQ ID NO: 2 and, therefore, Hair *et al.* has not described or suggested each and every element of amended or original Claim 2. Applicants thus respectfully request withdrawal of the rejection of Claim 2 under 35 U.S.C. section 102(a) as being allegedly anticipated by Hair et al.

Claim 4 stands rejected under 35 U.S.C. section 102(b) as being allegedly anticipated by Schiaffino (1995, GenBank Accession No. X83543). Amended Claim 4 describes an isolated nucleic acid molecule comprising a human nucleotide sequence that:(a) encodes the amino acid sequence shown in SEQ ID NO: 4; and(b) hybridizes under highly stringent conditions to the nucleotide sequence of SEQ ID NO: 3 or the complement thereof. The Action states (at page 10, line 11) "Schiaffino, discloses a nucleic acid molecule comprising a nucleotide fragment which shares identity with instant SEQ ID NO:3." This fragment does not however encode the amino acid sequence shown in SEQ ID NO: 4 and, therefore, Schiaffino has not described or suggested each and every element of amended or original Claim 4. Applicants thus respectfully request withdrawal of the rejection of Claim 4 under 35 U.S.C. section 102(b) as being allegedly anticipated by Schiaffino.

Claims 5 and 6 stand as rejected under 35 U.S.C. section 102(b) as being allegedly anticipated by Waterston (June 1998,GenBank Accession No. AC004958; reference "BI"). The rejection of Claim 5 has been respectfully avoided by the amendment of Claim 5 to read on the full-length nucleic acid sequence of SEQ ID NO:5. The sequence of Waterston matches only a portion of the nucleic acids of SEQ ID NO:5.

The rejection of Claim 6 as being allegedly anticipated by Waterston (June 1998,GenBank Accession No. AC004958; reference "BI") is in error. The Examiner's rejection of Claim 6 under Waterston is based solely on the hybridization element of claim and Claim 6 contains 2 limitations. Amended Claim 6 describes an isolated nucleic acid molecule comprising a human nucleotide sequence that:(a) encodes the amino acid sequence shown in SEQ ID NO: 6; and (b) hybridizes under highly stringent conditions to the nucleotide sequence of SEQ ID NO: 5 or the complement thereof. The examiner does not allege, nor would Waterston be expected to encode the amino acid sequence disclosed in SEQ ID NO: 6. Lacking such disclosure, it is largely irrelevant whether or not the

sequence described by Waterston *might* hybridize to the SEQ ID NO:5 under stringent or highly stringent conditions. Clearly, Waterston does not describe or suggest each and every element of amended or original Claim 6 as the nucleic acid sequence of Waterston cannot encode the amino acid sequence of SEQ ID NO: 6. Applicants, therefore, submit that the rejection of claims 5 and 6 under 35 U.S.C. § 102(b) under Waterston has been both avoided and overcome and respectfully request withdrawal of these rejections.

VIII. Conclusion

The present document is a full and complete response to the Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance, and such favorable action is respectfully requested. Should Examiner Ramirez have any questions or comments, or believe that certain amendments of the claims might serve to improve their clarity, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

May 22, 2001
Date

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Exhibit B

Marked Up Version of Amended Claims in U.S. Patent Application

Ser. No. 09/641,831

1. (Amended) An isolated nucleic acid molecule comprising [at least 24 contiguous bases of] a nucleotide sequence [first disclosed in the NHP gene] described in SEQ ID NO:1.

2. (Amended) An isolated nucleic acid molecule comprising a nucleotide sequence that:

(a) encodes the amino acid sequence shown in SEQ ID NO:2; and

(b) hybridizes under highly stringent conditions to the nucleotide sequence of SEQ ID NO:1 or the complement thereof.

3. (Amended) An isolated nucleic acid molecule comprising [at least 24 contiguous bases of] a nucleotide sequence [uniquely disclosed in the NHP gene] described in SEQ ID NO:3.

4. (Amended) An isolated nucleic acid molecule comprising a nucleotide sequence that:

(a) encodes the amino acid sequence shown in SEQ ID NO:4; and

(b) hybridizes under highly stringent conditions to the nucleotide sequence of SEQ ID NO:3 or the complement thereof.

5. (Amended) An isolated nucleic acid molecule comprising [at least 24 contiguous bases of] a nucleotide sequence [first disclosed in the NHP gene] described in SEQ ID NO:5.

6. (Amended) An isolated nucleic acid molecule comprising a nucleotide sequence that:

(a) encodes the amino acid sequence shown in SEQ ID NO:6; and

(b) hybridizes under highly stringent conditions to the nucleotide sequence of SEQ ID NO:5 or the complement thereof.